Remarks/Arguments

Record of Examiner Interview

Applicant's undersigned representative wishes to thank Examiner Spiegler for taking the time to discuss the subject application by telephone on May 14, 2003. During the interview, Examiner Spiegler and David Schodin discussed the state of the art as represented by the Uematsu and Kim references cited in the Office Action. The Examiner encouraged Mr. Schodin to submit an amendment comporting with the discussion. No agreement was reached, although Examiner Spiegler indicated that more consideration would be given to the points discussed.

Discussion Of The Obviousness Rejection

Kim fails to support the prima facie obviousness rejection

The Office Action states that Uematsu can be combined with Kim to arrive at the present invention.

Uematsu discloses that biological samples can be disrupted and the nucleic acids therein can be bound to silica-coated magnetic particles. Uematsu fails to teach or reasonably suggest that the silica-coated magnetic particles can be replaced by uncoated magnetic particles. Thus, for at least this reason, there is agreement that Uematsu does not anticipate the present invention.

The Kim reference discloses that metal oxides can be used as part of a method for purifying nucleic acids. It is agreed that Kim also discloses that the nucleic acids can be obtained from a variety of sources, such eukaryotic cells, prokaryotic organisms, yeast, and viruses. It is also agreed that Kim does not explicitly disclose purification from "blood, ocular lens fluid, cerebral spinal fluid, milk, ascites fluid, synovial fluid, peritoneal fluid, amniotic fluid, tissue, fermentation broth, and cell culture" without a prior "purification or precipitation step." Applicant respectfully submits that Kim also fails to reasonably suggest the same as demonstrated by the following analysis of the Kim reference.

Kim, Page 26, Lines 1-10 (i.e., claim 1)

The Office Action cites claim 1 of the Kim application (on page 26), which claim is directed to a method for purifying nucleic acids. The filed claim (but not allowed) contains two steps (a) releasing the nucleic acids from the sample into a solution, and (b) combining the solution with a metal oxide support. The ordinarily skilled artisan would recognize, the function of the claim in a patent application is to define the metes and bounds of what the patent applicant claims as his own. It is not intended to provide a complete recipe for practicing the claimed invention. The DETAILED DESCRIPTION of Kim discloses multiple steps that can be performed between steps (a) and (b), and therefore, it is neither surprising that claim 1 of the Kim application fails to disclose multiple steps that could be required to practice the claimed invention, nor would it have reasonably suggested to the ordinarily skilled artisan that these intermediate steps were

unnecessary. It cannot therefore be properly concluded that claim 1 reasonably suggests to the ordinarily skilled artisan that no purification or precipitation step need be performed between steps (a) and (b) of claim 1.

Kim, Page 2, Lines 27-37 (in the SUMMARY OF THE INVENTION)
The Office Action also cites page 2, lines 27-37 of the Kim reference. It is well-known that a common practice for U.S. patent applicants is to draft the SUMMARY section of a patent application by reciting, in narrative form, the elements of the independent claims. Occasionally, as in the Kim reference, additional description may be added to add some context to this claim language in narrative form. Because of this well-known fact, the ordinarily skilled artisan would immediately recognize the congruity between claim 1 of the Kim application and page 2, lines 27-37 of the Kim application and conclude that this passage is merely meant to reflect the elements of claim 1. That is, page 2, lines 27-37, are merely meant to describe in narrative form the metes and bounds of what Applicant Kim sought to claim his own, rather than to provide an enabling description of how to practice the claimed invention. Accordingly, page 2, lines 27-37 of the Kim reference does not place applicant Gundling's claimed invention into the possession of the public.

Kim, Page 3, Lines 22-30 (continuing in the SUMMARY OF THE INVENTION)
The Office Action also cites page 3, lines 22-30 of the Kim reference. This portion of the Kim reference consists of two sentences.

The first sentence essentially states that: the method of Kim is useful for any biological sample containing a desired nucleic acid that contains unwanted contaminants. This sentence merely provides a definition of what is meant by purification – the separation of desired nucleic acids from unwanted biomolecules.

The second sentence, which recites a variety of sources of nucleic acids, is routine in patent applications. It says that the nucleic acid to be purified can initially come from essentially any biological source. This sentence operates as a shield against interpretations that the nucleic acids can only be purified from those sources described in the working examples. More importantly, however, this passage is silent as to whether any purification steps must precede the binding of the nucleic acid from these samples to the metal oxide.

In summary, the Kim reference never explicitly teaches or implies that the purification steps used on in the working examples (and in particular Examples 8 and 10) are optionally

For the foregoing reasons, Kim fails to support the *prima facie* obviousness rejection.

Even assuming(arguendo) that Kim supports the prima facie rejection, the claimed invention would not have been obvious over Uematsu and/or Chomzynski in view of Kim

Further disclosures of Kim

The Kim reference is incomplete. It demonstrates how to purify nucleic acids from complex biological sources, but it never discusses the minimum requirements for purifying nucleic acids from any source. That is not problematic, however, because the Kim reference is a patent application, which is to be read in view of the common knowledge of those skilled in the art. The ordinarily skilled artisan, at the time Kim was filed understood how to perform multiple purification steps to partially purify nucleic acids from complex materials (See, T. Maniatis et al., Molecular Cloning: A Laboratory Manual, Cold Spring Harbor Laboratory (publ.), 1982, pages 366-369). Accordingly, there was no requirement for Kim to explicitly teach or disclose the common purification methods applied to biological samples prior to binding desired nucleic acids to solid supports in the art. This was within the common knowledge in the art.

However, taken as a whole, the ordinarily skilled artisan would recognize that Kim binds purified nucleic acids directly to the metal oxides, or when the nucleic acid is not purified, discloses the use of additional methods to partially purify the nucleic acid before binding the nucleic acid to the metal oxide. For example, in Fig. 1 and Example 8, Kim discloses the use (1) of alkaline lysis, neutralization, and centrifugation to precipitate cellular components (page 20, lines 9-12), (2) 50% isopropanol to precipitate the nucleic acids (page 20, lines 15-18), and (3) a lithium chloride precipitation step (page 20, lines 19-21), all prior to binding the nucleic acids to alumina (a metal oxide). While this is only a preferred embodiment, it is remarkably different than the claimed invention. Moreover, the use of 50% isopropanol and precipitation steps, is time-consuming and at each step the skilled artisan would expect loss of yield (of nucleic acid) and increased expense. Thus, it is apparent that the skilled artisan would interpret Kim on a whole as requiring prior precipitation steps when the nucleic acid to be purified is obtained from complex biological sources. Similarly, the ordinarily skilled artisan would not read this disclosure to reasonably suggest such steps were optional. In fact, the ordinarily skilled

Respectfully submitted,
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